IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	**Case #: 3:05-00444**
	)	**Judge Trauger**
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE THE TESTIMONY OF ALL DEFENDANTS' EXPERT WITNESSES OTHER THAN DR. GIBBONS CONCERNING THE FDA ALERT AND RELATED FDA SUBJECTS, OR, IN THE ALTERNATIVE, TO EXCLUDE THE TESTIMONY OF DR. GIBBONS

Plaintiff Ruth Smith moves to limit Defendants to that which they represented to the District Court in Massachusetts was needed — an expert report to rebut the FDA Alert on Suicidality and Epileptic Drugs and the FDA meta-analysis and committee review of such Alert and meta-analysis. Subsequent to their request for such a rebuttal expert, three of Defendants other expert witnesses, namely, Dr. Janet Arrowsmith-Lowe, Dr. Sheila Weiss-Smith and Dr. Anthony Ruggieri, opined on this specific topic, and testified that they were qualified and competent to do so, in direct contradiction to what Defendants represented to the District Court in Massachusetts. Moreover, not only did Defendants make misrepresentation as to their need for a rebuttal witness to the Massachusetts District Court, the supplemental reports of these three experts violate the scheduling orders of the District Court in Massachusetts regarding general

causation expert witnesses. This Court should exclude the testimony of all defense experts other than Dr. Gibbons concerning the FDA Alert and related FDA subjects for the reasons set forth in detail below, or, alternatively, the Court should exclude Dr. Robert Gibbons.

I. INTRODUCTION

Defendants named three expert witnesses on general causation who have expertise in the FDA, epidemiology, and statistics, namely Dr. Arrowsmith-Lowe, Dr. Weiss-Smith, and Dr. Ruggieri. Each expert submitted expert reports in 2007 in which each essentially opined that the FDA had concluded that Neurontin did not pose a risk of suicidality in off-label populations because the FDA had not issued any alerts or required any label changes to that effect. On January 31, 2008, the FDA did issue an Alert exactly to that effect, alerting physicians that its analysis of random controlled trials disclosed that anti-epileptic drugs, including Neurontin, doubled the risk of suicide over placebo.

Plaintiff's experts supplemented their reports to incorporate the FDA Alert. Defendants re-deposed Plaintiff's experts on their supplemental reports. The three defense experts, however, did not supplement their reports at that time to address the FDA Alert. Instead, on April 10, 2008, Defendants filed a "Motion For Leave To Name A Rebuttal Expert" (Case No. 04-10981, D. Mass,. ECF Doc. # 1218), to add and designate Dr. Robert Gibbons as a rebuttal expert to opine upon the FDA Alert. The defense expressly based their motion on the representation that Dr. Gibbons was *uniquely qualified:*

> Defendants are prepared to designate Dr. Robert Gibbons as a rebuttal expert. Dr. Gibbons is uniquely qualified to opine on plaintiffs' experts' reliance on the Alert, as well as FDA's analysis and methodology and their scientific reliability.
>
> * * *
>
> If defendants' motion for leave is granted, Dr. Gibbons will opine on the scientific validity of reliance on the FDA Alert for *general causation opinions*, limitations

> of pooled data analyses in general and specific to FDA's analysis, improper inferences plaintiffs make on the basis of the Alert, and analyze any data forthcoming from FDA in advance of the FDA Advisory Committee meeting.

Case No. 04-10981, D. Mass. ECF Doc. # 1218 at 10.

On April 17, 2008, Judge Patti B. Saris granted Defendants' motion. Plaintiffs filed an opposition (Case No. 04-10981, D. Mass,. ECF Doc. # 1237) on April 24, 2008, along with a request for clarification of the April 17, 2008 order. On April 30, 2008, the Court entered the following order:

> Judge Patti B. Saris: Electronic ORDER entered regarding 1231 Emergency MOTION for Order to seek clarification of April 17, 2008 electronic order granting 1217 motion for leave to name a rebuttal expert by Members of the Plaintiffs Product Liability Steering Committee. "I read plaintiffs' memo, but will still permit a rebuttal expert report involving only the FDA alert, which is a key finding in this case. I will also be sending a letter to the FDA asking for its i[n]put." (Alba, Robert) (Entered: 04/30/2008).

Then, much to Plaintiff's surprise, in November 2008, defense experts Dr. Arrowsmith-Lowe, Dr. Ruggieri, Dr. Weiss-Smith and Dr. Gerald Sanacora provided extensive and almost identical general causation opinions concerning the FDA Alert, meta-analysis, and advisory committee supplemental disclosures.

None of these experts was uniquely qualified enough in April 2008 to give those opinions on Defendants' behalf — the defense told the District Court in Massachusetts that it was Dr. Gibbons who was uniquely qualified in this area. Unless Defendants misrepresented to the Massachusetts District Court the qualifications necessary to form opinions about the FDA safety alert and meta-analysis, these other experts are not qualified and their opinions on that subject should be struck for failure to meet the requirements of Fed. R. Evid. 702 and *Daubert v. Merrill Dow Pharmaceutical, Inc.*, as well as being cumulative and one year too late for general causation opinions under the scheduling order.

Conversely, if these experts were qualified, and at least three of them testified that they were, then Defendants misrepresented to the District Court in Massachusetts the need to name Dr. Gibbons as a rebuttal expert. In that case, Dr. Gibbons should be struck as a rebuttal expert. It should be noted that Products Liability Plaintiffs have filed a separate *Daubert* motion to strike Dr. Gibbons' testimony as unreliable under Fed. R. Evid. 702 and 703 and *Daubert v. Merrill Dow Pharmaceutical, Inc.*, as one of Plaintiffs' Motions *in Limine* that is still pending before Judge Patti B. Saris in the District Court of Massachusetts. Case No. 04-10981, D. Mass., ECF Doc. # 2121.

If this Court does not disallow all of the experts to testify concerning the FDA Alert and meta-analysis, the Court should limit such testimony to one witness so that it is non-cumulative under Fed. R. Evid. 403.

II. ARGUMENT

A. Initially Disclosed Defense Experts Were Capable of Opining Upon the FDA Alert Thus Obviating the Need For Rebuttal Expert Dr. Robert Gibbons

The experts retained by Defendants maintained that they possessed the requisite qualifications to form opinions and testify about the FDA Safety Alert and meta-analysis. Dr. Janet Arrowsmith-Lowe, a physician, an elected Fellow of the American College of Epidemiology, and a former FDA Medical Review Officer testified:

> Q. Are you aware that in the end of January of 2008, the FDA came out with an alert associated with anticonvulsant drugs and suicidality?
>
> A. Yes, I'm aware of that.
>
> Q. Have you read that alert?
>
> A. Yes.
>
> Q. Okay. Are you aware that in May of 2008, the FDA published a statistical review associated with that alert?

A. I'm aware of that, yes, of that statistical review, yes.

Q. Did you review that statistical review?

A. Yes, I've read it.

Q. Okay. Are you aware that in July of 2008, the FDA convened an advisory committee to discuss what proposed label changes associated with the anticonvulsants and suicidality?

MR. BARNES: Objection, incomplete question regarding what the advisory committee did. But go ahead and answer.

THE WITNESS: I'm aware that FDA convened a joint advisory committee, yes, to discuss AEDs and suicide.

BY MR. ALTMAN:
Q. Okay. Did you review that transcript?

A. Yes.

Q. At the time the FDA alert came out, were you qualified to render opinions based upon the FDA alert?

A. I don't understand what you're asking me.

Q. Were you qualifying to render opinions concerning the FDA alert and what it means and what it meant for Neurontin?

A. I believe so, yes.

Q. When the statistical analysis came out in May of 2008, were you qualified to render opinions based upon the FDA's statistical review and its adequacy and completeness and appropriateness?

A. Yes.

Q. When the -- when you read the advisory committee transcript in July -- from July of 2008, were you qualified to render opinions based upon what was discussed at the advisory committee?

A. In my opinion, yes.

Declaration of Kenneth B. Fromson, Ex. A at 127:19-129:11.

Dr. Alexander Ruggieri, a board certified physician in Internal Medicine and Rheumatology, and expert in pharmacovigilance and pharmacoepidemiology testified:

> Q. At the time that alert came out, do you believe you possessed the requisite qualifications to discuss that alert and how to interpret that alert?
>
> MR. BARNES: Objection. He had the requisite qualifications as a physician and drug safety expert to interpret the safety alert?
>
> BY MR. ALTMAN:
> Q. Do you have the -- do you possess -- did you possess the requisite qualifications to interpret and comment upon the alert?
>
> A. Yes.
>
> Q. Okay. So that's not some new skill you just obtained between then -- you could have done it back in January, correct?
>
> A. I don't understand the question.
>
> Q. Bad question. Forget it. Strike that.
>
> MR. BARNES: In January -- I think he answered in January he was qualified to interpret the safety alert. He answered that already. That was your question.
>
> MR. ALTMAN: That's fine.
>
> MR. BARNES: Yeah. He's answered that.
>
> MR. ALTMAN: Okay.
>
> BY MR. ALTMAN:
> Q. Do you believe you possess the qualifications to express opinions based upon the statistical analysis done by the FDA in response to that alert?
>
> A. Yes.

Fromson Decl., Ex. B at 98:23-100:22. Dr. Ruggieri further testified:

> Q. Were you -- do you possess the qualifications to discuss -- to render opinions based upon what was discussed in that advisory committee meeting?
>
> A. Yes.

Fromson Decl., Ex. B at 101:12-101:20.

Sheila Weiss-Smith, PhD., a pharmacoepidemiologist and a Fellow of the International Society of Pharmacoepidemiology, similarly testified:

> Q Okay. Are you qualified to review the FDA's statistical analysis in the advisory committee transcript?
>
> A Excuse me?
>
> Q Do you believe that you are qualified to have reviewed the FDA statistical review in the advisory committee and render opinions?
>
> A Absolutely. That's what I do for the FDA. I often sit on these type of advisory committees. I couldn't sit on this one because I had already been retained on this case.
>
> Q Do you believe that you were qualified to do so in January when we took your deposition last?
>
> A Excuse me?
>
> Q Your qualifications to review this information, is that a new found qualification or is that something that you possessed back in January when we took your deposition last time?
>
> A I believe I was qualified in January to sit on the advisory committee and review the materials. Yes. I think I've been qualified for years to do so.
>
> Q Were you asked by Pfizer to review those materials within January -- in the January timeframe right after it came out?
>
> A I was provided by –
>
> MR. BARNES: Answer the question.
>
> A By Pfizer? Pfizer didn't -- I didn't directly talk to anyone at Pfizer about this case. Period.
>
> Q Were you asked by counsel to review that FDA and render an opinion?
>
> A They provided me with the alert and the information.
>
> Q Did they ask you to do anything with it?
>
> A Just to reread it.

Q When the statistical review -- when did you first see the FDA statistical review?

A When did I see it? When it was -- after it was made available to the public on their web site.

Q So you didn't see it before then?

A No, I only saw it when it was made available.

Q Do you know if Pfizer had that document before it was made publicly available?

A I'm not aware.

Q Were you asked to ever review it at that time?

MR. BARNES: What time?
Q At the time it became publicly available. When we're talking about the FDA statistical review?

A Was I asked to look at it? I think I had already looked at it as soon as it became available because I wanted to put the alert in January in context. So I was very interested in what they said.

Q When was the first time you were asked to put down on a piece of paper an opinion based upon the FDA alert?

MR. BARNES: Objection. We have a stipulation in this case where drafting of expert reports is not the subject of examination. So I'll instruct her not to answer that question.

MR. ALTMAN: I'm not asking about the drafting. I'm asking when she was asked to do it. That's not the drafting.

MR. BARNES: That's a different question.

MR. ALTMAN: I asked when was the first time you were asked to opine upon the FDA alert.

MR. BARNES: That's a different question. You may answer that one.

A I believe it was in early fall.

> Q Okay. When was the first time you were asked to render any opinions on the advisory committee meeting and the transcript and the discussions that took place?
>
> A I believe it was around the same time.
>
> Q Have you ever had any direct discussions with Dr. Robert Gibbons?
>
> A No.
>
> Q Do you believe that you are -- you're aware that Dr. Gibbons did a pharmacoepidemiologic study of the pharmametrics data, correct?
>
> A Yes, I'm aware of it.
>
> Q If you had been given that raw data as he was, do you believe you could have done a similar study?
>
> A Yes.
>
> Q So you pretty much see yourself as kind of colleagues, same general qualifications?
>
> A I consider us colleagues. He's a biostatistician and I'm an epidemiologist. We typically work together on teams.

Fromson Decl., Ex. C at 60:6-63:21.

There is no question that the expertise of these designated experts was sufficient to render opinions on the FDA Alert and following proceedings. Furthermore, in February 2008, Defendants updated the expert disclosures for all of their retained experts:

> Each of the aforementioned experts has reviewed and considered the U.S. Food and Drug Administration (FDA) Alert relating to antiepileptic drugs . . . .Further, each of the aforementioned defense experts shall review and consider the data, analyses and other documents as they become available relating to FDA's analysis of drugs identified in the FDA Alert, which may supply additional bases for their opinions on general causation and /or may form the basis for additional opinions once considered . . . .

Fromson Decl., Ex. D.

B. Several Defense Experts Rendered Extensive Opinions on the FDA Alert and Proceedings, Contrary To Representations By Defendants To The Court

Although Defendants represented to the District Court in Massachusetts that Dr. Gibbons was necessary as a rebuttal expert because he was "uniquely qualified" to render opinions on the FDA Alert and further proceedings, several of Defendants' experts rendered these very opinions in their November, 2008 supplemental disclosures.

Of the 14 pages of Dr. Arrowsmith-Lowes' report (Fromson Decl., Ex. E), pages two through five concerned the FDA Alert. Dr. Ruggieri dedicated pages three to six of his 15-page report to the FDA alert. Fromson Decl., Ex. F. Dr. Weiss-Smith's supplemental report (Fromson Decl., Ex. G), consumed pages 2 to 16 of her 34-page report concerning the FDA. Lastly, Dr. Sanacora's supplement report (Fromson Decl., Ex. H) addresses the Alert on pages three to four and 15 to 19 of his 23-page report. Each of these reports consists of substantive opinions based upon each expert's extensive analysis of the FDA Alert.

"As 'gatekeeper,' the trial judge is imbued with discretion in determining whether or not a proposed expert's testimony is admissible, based on whether it is both relevant and reliable." *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426 (6th Cir. 2007) (citing to *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999)). "By defining evidentiary reliability in terms of scientific validity, the *Daubert* Court instructed district courts that their primary function as 'gatekeepers' is "to determine whether the principles and methodology underlying the testimony itself are valid" - not to second guess the validity of conclusions generated by otherwise valid methods, principles, and reasoning." *Pride v. BIC Corp.*, 218 F.3d 566, 577 (6th Cir. 2000). Moreover the Sixth Circuit has stated regarding the qualifications required for an expert witness:

> [I]n addition to requiring that a proposed expert's testimony be "reliable," Rule 702 requires that the expert's testimony assist the trier of fact. This requirement has been interpreted to mean that scientific testimony must "fit" the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in

> which the expert will testify. In short, under Daubert and its progeny, a party proffering expert testimony must show by a "preponderance of proof" that the expert whose testimony is being offered is qualified and will testify to scientific knowledge that will assist the trier of fact in understanding and disposing of issues relevant to the case.

Id. at 578 (citations omitted).

The threshold issue for testimony under Fed. R. Evid. 702 is that the witness is qualified as an expert. If Defendants' representations to this Court is that Dr. Gibbons is "uniquely qualified" to render opinions on the FDA Alert, then the other experts must be unqualified to do so. Therefore, under Fed. R. Evid. 702, any opinions by any expert on the FDA Alert, other than Dr. Gibbons, must be struck.

C. If Defendants' Initial Experts Were Qualified to Render Opinions on FDA Alert and Proceedings, Defendants Misrepresented the Necessity for Dr. Gibbons as a Rebuttal Expert and He Should Be Struck

The District Court in Massachusetts allowed Dr. Gibbons as a rebuttal expert based upon Defendants' representations that he alone was uniquely qualified to render opinions on the FDA Alert and meta-analysis. However, given that Defendants have continued to maintain that their already-designated experts were qualified to render opinions on the FDA Alert, Dr. Gibbons was not necessary as a rebuttal expert. The Court should reconsider the District Court of Massachusetts' Order and exclude Dr. Gibbons as a necessary late addition to the defense stable.

CONCLUSION

Therefore, this Court should exclude the testimony of all defense experts other than Dr. Gibbons concerning the FDA Alert and related FDA subjects for the reasons set out above. or, alternatively, the Court should exclude Dr. Gibbons because Defendants misrepresented to the Court the necessity of using him as an expert witness, and should order Defendants to proceed

with the experts who were timely designated and are by Defendants' admissions and their testimony as qualified to form and express the opinions Dr. Gibbons.

Dated: April 16, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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